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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel, RICARDO N. SARLI, M.D. and ELAINE L. EPHLIN Plaintiffs	: Case No.	4:CV 16-1810 JUDGE BRANN : FILED IN CAMERA AND : UNDER SEAL
THE GUTHRIE CLINIC, a domestic non-profit corporation and THE GUTHRIE MEDICAL GROUP, P.C., a professional corporation Defendants	:	: JURY TRIAL DEMANDED

COMPLAINT

This action, filed pursuant to the *qui tam* provisions of the False Claims Act, as amended, (31 U.S.C. §§3729 *et seq.*) and principles of common law, is based on a scheme by the Defendants to defraud the United States the Federal Medicare and Medicaid Programs and the American taxpayers of large sums of money through fraud, waste, abuse, mismanagement, and gross neglect while the Defendants acted as Medicare and Medicaid providers responsible to follow the

rules and regulations relating to reimbursement of Medicare and Medicaid Claims for medical treatment and services.

Plaintiffs/Relators, by and through the undersigned counsel, and acting on behalf of and in the name of the United States of America, allege as follows:

THE PARTIES

1. The Plaintiffs/Relators are citizens of the Unites States of America. Plaintiff/Relator Ricardo N. Sarli, M.D., is a resident of the State of New York. Plaintiff/Relator Elaine L. Ephlin is a resident of the Commonwealth of Pennsylvania. The Plaintiffs/Relators bring this suit on their own behalf and in the name of the United States of America pursuant to 31 U.S.C. §3730(b).

2. The United States administers federal Medicare and Medicaid programs through its agency, the Department of Health and Human Services (DHHS), and the Centers for Medicare and Medicaid Services (CMS) formerly known as the Division of Health Care Financing Administration (HCFA). CMS/HCFA is authorized to enter into and administer contracts on behalf of DHHS and the United States of America. Inclusive in CMS/HCFA's contracting authority is the responsibility for administering the Federal Medicare and Medicaid programs and the reimbursement of Medicare and Medicaid Claims processed by Medicare contractors.

3. The Defendant Guthrie Clinic is a Pennsylvania domestic nonprofit corporation with its registered office at One Guthrie Square, Sayre, Pennsylvania, 18840.

4. The Defendant Guthrie Medical Group, P.C., formerly known as the Guthrie Clinic, LTD, is a professional corporation with its registered office at One Guthrie Square, Sayre, Pennsylvania, 18840.

5. The Defendant Guthrie Clinic portends to operate as an integrated Section 501(c)(3) health care delivery system which includes the corporation and other entities that are directly or indirectly controlled by the corporation including, without limitation, the Robert Packer Hospital, Corning Hospital, Troy Community Hospital, Inc., Towanda Memorial Hospital, Robert Packer Hospital School of Nursing, Guthrie Home Care, Guthrie Hospice, Sayre House of Hope, Donald Guthrie Foundation, Twin Tiers Management Corporation, Med Supply Depot and Guthrie Medical Group, P.C., all of which, excepting the Corning Hospital, operate in the Middle District of Pennsylvania.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this matter under 31 U.S.C. §3732(a) and 28 U.S.C. §§1331 and 1345.

7. The Plaintiffs/Relators have direct and independent knowledge, within the meaning and definition of 31 U.S.C. §3730(e)(4)(B), derived through and from

the Plaintiffs/Relators' employment with the Defendants and their own information on which the allegations set forth in this Complaint are based, and the Plaintiffs/Relators are voluntarily providing this information to the government as part of the disclosure statement filed contemporaneously with this Complaint. None of the allegations set forth in this Complaint or accompanying disclosure statement are based on a public disclosure of allegations or transactions in a criminal, civil, or administrative hearing; in a congressional, administrative, or general accounting office report, audit, or investigation; or from the news media.

8. Venue in the Middle District of Pennsylvania is proper under 31 U.S.C. §3732(a) and 28 U.S.C. §1931(b)(c). The claims for services which are the subject matter of this Complaint are all processed by the government's fiscal intermediaries located in and around the Middle District of Pennsylvania and Central New York State. In addition, the majority of operations of the Defendants Guthrie Clinic and Guthrie Medical Group, P.C., (hereinafter jointly "Guthrie"), are located and provided within the Middle District of Pennsylvania.

THE FEDERAL MEDICARE AND MEDICAID PROGRAMS

9. The Medicare program was enacted in 1965 and is the Federal Health Insurance Program contained in Title XVIII of the Social Security Act, 42 U.S.C. §1395 *et seq.*

10. The Medicare Program provides health insurance to Social Security recipients 65 years old and over and to those permanently disabled as defined under the Social Security Act.

11. The Medicare Program has developed into the largest insurance program in the world and is entirely a federal program. While the federal government pays the actual benefits, Medicare operates much like private health insurance in that it only pays a portion of the cost of medical care. Those eligible for coverage must first pay an initial amount (called a deductible) and part of the medical fees (called co-insurance) before Medicare pays.

12. Part B of the Medicare Program covers supplementary medical benefits which include physicians services, laboratory testing services, and durable medical equipment services, and insofar as is relevant in this case, these are the types of services provided by Guthrie.

13. Part A of the Medicare Program, which covers medical services involving inpatient hospitalization, nursing facilities, and some home healthcare, is financed solely through payroll deductions of current workers. Part B of the Medicare Program, which is involved in this case, is funded by monthly premiums paid by Medicare beneficiaries which are matched with general revenue funds of the United States of America. Both programs are funded by federal money within the meaning of the False Claims Act. 31 U.S.C. §3729 *et seq*

14. Anyone eligible for Medicare is automatically eligible for Part A. Part B coverage is optional and participants must pay a monthly premium. Recipients receiving Social Security normally opt to have their Part B payment deducted from their monthly Social Security benefit checks, and this amount does not fully cover the services but rather requires additional federal money to be contributed thereby clearly invoking the provisions of the False Claims Act. 31 U.S.C. §3729 *et seq*.

15. The Federal Government has promulgated rules and regulations relating to the billing of services, and CMS/HCFA's fiscal intermediary during this period of time contractually charged with enforcing CMS/HCFA contracts in the state of Pennsylvania was Novitas Solutions, Inc., formerly known as Highmark Medicare Services, Inc. Novitas in its capacity as the government's fiscal intermediary has also promulgated rules and regulations covering providers of services under Medicare Part B. These rules are published as reference manuals known as manuals and billing guides.

16. These rules have become well known and established in the medical community and determine the amount of compensation that a provider of medical services, such as Guthrie, will be paid in federal money for services rendered and billed under the Medicare program.

17. The integrity and solvency of the Medicare system, as well as its ability to continue to deliver medical services, depends on providers such as Guthrie complying with these rules and exercising honesty and integrity when reporting and coding various medical services for payment.

18. Medicaid in the Commonwealth of Pennsylvania and New York State is a federally assisted grant program for the states enabling them to provide medical assistance and related services to needy individuals. CMS administers the Medicaid program on the federal level. The states directly pay for Medicaid services and then obtain a federal reimbursement share through accounts drawn from the United States Treasury. 42 CFR §§430.0 – 430.30 (1994). The federal share of each state's Medicaid program is at least 50%.

19. Guthrie submitted claims and/or received false or fraudulent funds from the Medicaid programs in Pennsylvania and New York State.

20. Guthrie violated its duty to properly report and code medical services and, in that way, made false claims and false statements in violation of the False Claims Act as demonstrated by the following examples.

I. TRIPLED CLAIMS FOR MISCELLANEOUS LABORATORY SERVICES PERFORMED BY REFERENCE LABORATORIES

21. Guthrie routinely sends laboratory specimens to laboratories outside of the Defendant's ownership and/or control (i.e., "reference labs") for testing.

A significant number of these tests are routinely classified as miscellaneous laboratory tests via the Epic/Beaker laboratory information system ("LIS").

22. Once testing is complete, the reference lab bills Guthrie for its laboratory services.

23. Guthrie's medical billing system allows manual entry of billing amounts for miscellaneous laboratory tests.

24. Guthrie, through its directors, officers and employees, consistently marked up the reference lab's bill by three times the amount billed by the reference lab and thereafter submitted the tripled bill to Medicare's fiscal intermediary or the Medicaid program for payment or reimbursement.

25. This is a misrepresentation of services which results in money being improperly paid to Guthrie by the Medicare and Medicaid programs.

II. UNBUNDLING AND MISREPRESENTATION OF LABORATORY TESTS

26. Certain laboratory tests such as cholesterol subsets ("LDL") and magnesium panels are routinely ordered by Guthrie providers to obtain information regarding a patient's condition.

27. These tests contain "bundled" information concerning the patient (e.g., lipid and LDL information).

28. Guthrie routinely ordered separate tests in lieu of bundled testing because of the greater amount of revenue generated by separate testing (i.e., a lipid test and an LDL test).

29. This process is known as "unbundling" and results in excessive payments being made by the Medicare and Medicaid programs.

III. FAILURE TO COLLECT CO-PAY

30. As an employment incentive, Guthrie offers a comprehensive health insurance plan to its employees and their dependents.

31. The plan requires co-payments by employees for certain medical services such as hospital stays, doctor visits, and laboratory services.

32. Guthrie insured employees are not required to make co-payments for services (e.g., laboratory services) and/or receive a reduced fee for services while other patients (i.e., Medicare or Medicaid insured patients) are required to make the co-payment or pay a higher fee.

33. This preferential treatment by Guthrie of its employees and their dependents who are covered by Guthrie's health insurance results in greater amounts being paid by patients covered by Medicare and Medicaid for similar services which is a violation of Medicare and Medicaid's rules and regulations.

IV. OVERUTILIZATION OF LABORATORY AND DIAGNOSTIC TESTS

34. Defendant Guthrie Medical Group, P.C. operates the Guthrie Clinic Laboratory (NPI No. 1649225855) at the Sayre main campus which performs the majority of laboratory tests ordered by Guthrie providers.

35. For the eleven (11) month period from March 2015 through January 2016, the Relators documented at least 937 mislabeled specimens at the Sayre main campus laboratory causing tests to be reproduced and unnecessary costs to be incurred.

36. The above incidents are just a sampling of the patient identification and specimen labeling errors that the relators have observed since Guthrie summarily switched its LIS to Epic/Beaker in March 2014.

37. These patient identification and specimen labeling errors result in the Medicare and Medicaid programs paying for laboratory tests which are wasteful and useless and which often require retesting at the expense of the above federally funded programs.

V. IMPROPER BILLING FOR PHLEBOTOMISTS IN NURSING HOMES AND THE PROVISION OF FREE COMPUTER SOFTWARE

38. Guthrie describes itself as an integrated health care system which operates hospitals in Sayre, Pennsylvania, Troy, Pennsylvania, Towanda, Pennsylvania, and Corning, New York.

39. After acquiring Corning Hospital, Guthrie maintained a laboratory in Corning to address that hospital's and the surrounding area's needs.

40. In or about 2014, Guthrie entered into negotiations for laboratory services with Bethany Village, a skilled nursing facility located in Horseheads, New York.

41. As a result of the negotiations, Guthrie and Bethany Village entered into an Agreement for Guthrie to provide laboratory services to Bethany Village.

42. In exchange for the above agreement, Guthrie agreed to provide phlebotomists to perform blood specimen collection at the Bethany Village facility despite the presence of personnel at the Bethany facility who were qualified to draw blood from residents.

43. Guthrie implemented a practice of sending phlebotomists from Sayre, Pennsylvania, to perform blood draws at Bethany Village who would transport the specimens back to Guthrie's laboratory in Sayre, Pennsylvania, for processing.

44. The specimens were transported to Sayre despite the availability of a qualified laboratory at the Corning hospital.

45. It is believed and therefore averred that transporting the specimens to the Sayre laboratory as opposed to the Corning laboratory (which is 11miles closer) was done to charge Medicare/Medicaid extra mileage.

46. It is further believed and therefore averred that Guthrie provided Bethany Village with free computer software so that Bethany Village could view immediate results for tests once testing was performed by the Sayre campus laboratory in violation of the Stark Act, 42 U.S.C. §1395 and the Anti-Kickback law, 42 U.S.C. §1320a-7b..

VI. IMPROPER USE OF RELATOR SARLI'S NPI AND MEDICAL LICENSE NUMBERS AFTER HIS RESIGNATION AS LABORATORY MEDICAL DIRECTOR

47. On March 17, 2014, Relator Sarli began employment with Guthrie as Chairman of the Department of Pathology.

48. As Chairman, Relator Sarli also served as Laboratory Medical Director for Guthrie.

49. As Laboratory Medical Director, Relator Sarli was responsible for the overall operation and administration of Guthrie's laboratories including compliance with Medicare/Medicaid conditions of participation and billing for medical services provided.

50. In addition, any billing submitted by Guthrie to Medicare or Medicaid for payment relating to laboratory services were billed under Relator Sarli's National Provider Identification (NPI) and medical license numbers.

51. On June 23, 2015, Relator Sarli resigned as Chairman of the Pathology Department and as Laboratory Medical Director due to Guthrie's

continuous refusal to address his concerns regarding substandard laboratory practices which affected patient safety and laboratory billing irregularities.

52. After resigning as Chief of Pathology and Laboratory Medical Director, Relator Sarli continued to work for Guthrie as a staff pathologist at Guthrie's request.

53. On November 23, 2015, Relator Sarli was summoned to Guthrie's administrative office and terminated due to "lack of funding for his position."

54. From June 23, 2015, until February 17, 2016, Guthrie continued to use Relator Sarli's NPI and medical license numbers on bills which it submitted to Medicare and Medicaid for payment of laboratory services.

55. Guthrie's continued use of Relator Sarli's NPI and medical license numbers on bills for laboratory services after his resignation and termination was done without Relator Sarli's permission or authorization, contrary to the Clinical Laboratory Improvement Act of 1988 (CLIA), 42 U.S.C. §§263 *et seq*.

COUNT I
False Claims Act: Presentation of False Claims

56. The allegations of paragraphs 1 through 54 are incorporated by reference as if fully set forth herein.

57. The Defendants knowingly presented false and fraudulent claims for payment, or caused false or fraudulent claims to be presented to officers or

employees of the United States government in violation of 31 U.S.C. §3729(a)(1). As a result of the Defendants' conduct, the United States suffered actual damages.

COUNT II
False Claims Act: Presentation of False Statements

58. The allegations of paragraphs 1 through 56 are incorporated by reference as if fully set forth herein.

59. The Defendants knowingly made or used or caused to be made or used false records or statements in order to get the payment or approval of false or fraudulent claims paid or approved by officials of the United States government in violation of 31 U.S.C. §3729(a)(2). As a result of the Defendants' conduct, the United States suffered actual damages.

COUNT III
False Claim Act: Conspiracy to Defraud the Government

60. The allegations of paragraphs 1 through 58 are incorporated by reference as if fully set forth herein.

61. The Defendants, through their agents and employees, entered into a conspiracy to defraud the United States government by getting false and fraudulent claims allowed and paid in violation of 31 U.S.C. §3729(a)(3). As a result of Defendants' conduct, the United States suffered actual damages.

COUNT IV
Unjust Enrichment

62. The allegations of paragraphs 1 through 60 are incorporated by reference as if fully set forth herein.

63. As a result of the aforesaid acts, omissions, and conduct, the Defendants have been unjustly enriched at the expense of the United States, under circumstances requiring that in equity and good conscious, the money should be returned to the United States or to overcharged beneficiaries.

COUNT V
Payment by Mistake of Fact

64. The allegations of paragraphs 1 through 62 are incorporated as if fully set forth herein.

65. As a result and the consequences of the aforesaid conduct, the United States paid Medicare Part B and Medicaid claims that were not properly payable.

66. At the time the United States made such payments, government officials were unaware of the wrongful conduct of Defendants. Had the United States known that the Defendants had devised a scheme outlined above whereby the Defendants would bill for fees which exceeded the fees allowed by the Medicare and Medicaid fee schedules for a particular locality, the United States would not have approved the payment of such funds.

COUNT VI
Retaliation

67. The allegations of paragraphs 1 through 65 are incorporated by reference as if fully set forth herein.

68. Relator, Ricardo N. Sarli, M.D., is a pathologist with prior experience in assisting government agencies investigating laboratory regulatory issues and in assisting medical practices identifying and improving regulatory compliance and patient safety issues.

69. In October of 2013 Relator Sarli was hired by the Guthrie as Chairman of the Department of Pathology.

70. As a part of his employment for Guthrie, Relator Sarli was asked to evaluate the Defendants' laboratories and provide two (2) and five (5) year plans for addressing deficiencies in the laboratories including, but not necessarily limited to, regulatory compliance and patient safety issues.

71. Relator Sarli's plans were fully approved by the Defendants prior to his start of employment.

72. From the onset of his employment on March 17, 2014, it became clear to Relator Sarli that the Defendants were not willing to implement his approved plans to correct laboratory deficiencies and adhere to regulatory compliance standards.

73. Relator Sarli specifically identified to Defendants' senior leadership a pattern of improper billing which greatly concerned him since, as Laboratory Medical Director, all billing was routinely submitted to third party payers using his name, NPI, and medical license numbers.

74. In addition to billing impropriety, Relator Sarli also reported his concerns regarding patient safety, by way of limited example, the excessive number of identified specimen mislabeling errors and patient misidentification errors.

75. Relator Sarli's concerns regarding Defendants' lack of compliance with laboratory regulations and substandard laboratory operations were confirmed by an evaluation team from the College of American Pathologists ("CAP"), which performed an accreditation readiness assessment in October, 2014 at Relator Sarli's request.

76. Defendants' response to Relator Sarli's concerns and the CAP assessment was to intentionally remove or alter documentation of reported incidents of laboratory error and to increase hostility toward Relator Sarli and his compliance efforts.

77. Due to the Defendants' continuous refusal to address Relator Sarli's concerns as described above, Relator Sarli resigned as Chairman of Guthrie's Department of Pathology and Laboratory Medical Director on June 23, 2015.

78. Following his resignation, Relator Sarli continued to work for Guthrie as a staff pathologist at Guthrie's request.

79. Despite his resignation as Chairman of the Pathology and as Laboratory Medical Director, Relator Sarli continued to advocate for reforms in the laboratory.

80. On or about November 25, 2015, Relator Sarli and other pathologists were scheduled to meet with Defendants' administration to discuss ongoing concerns in the laboratory and to bring forth possible solutions to rectify regulatory compliance and patient safety issues.

81. While at work on November 23, 2015, Relator Sarli was summarily terminated from employment by the Defendants and was abruptly escorted from the clinic building by security with only a limited opportunity to retrieve his personal items.

82. Relator Sarli believes and therefore avers that his termination was directly related to his continuous efforts to bring his concerns regarding patient safety, regulatory compliance, and the Defendants' improper billing practices to the attention of the Defendants' administration.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs/Relators acting on behalf of and in the name of the United States of America, demand and pray that judgment be entered in favor of the United States and jointly and severally against the Defendants on Counts I through VI as follows:

1. On Count I (False Claims Act - Presentation of False Claims) for treble the amount of damages suffered by the United States plus civil penalties of $10,000 for each false claim;

2. On Count II (False Claims Act - Presentation of False Statements) for treble the amount of the damages suffered by the United States plus civil penalties of $10,000 for each false statement or false record;

3. On Count III (False Claims Act - Conspiracy to Defraud the Government) for treble the amount of the damages suffered by the United States plus civil penalties of $10,000 for each false statement or false record;

4. Count IV (Unjust Enrichment) for restitution and repayment of all funds by which the Defendants have been unjustly enriched plus pre-judgment interest;

5. On Count V (Payment of Mistake of Fact) for return of all government funds paid by mistake or through the erroneous acts of Defendants plus pre-judgment interest;

6. On Count VI (Retaliation) the Relator, Ricardo N. Sarli, M.D., claims all relief available under 31 U.S.C.S.§3730(h) for retaliation including, but not limited to, twice the amount of back pay, front pay, interest on back pay, damages for lost reputation, and all other appropriate remedies;

7. For all accrued interest, costs, and attorneys fees; and

8. For such other and further relief as the court deems just and equitable. Moreover, Plaintiffs/Relators, on their own behalf, demand, and pray that an award be made in their favor as follows:

9. For 25% of the proceeds collected by the United States if the United States intervenes and conducts this action or for 30% of the proceeds if the United States does not intervene;

10. For an amount for reasonable expenses necessarily incurred by the Relators in the prosecution of this action;

11. For all reasonable attorney fees and costs incurred by the Relators in connection with these proceedings; and

12. For such other and further relief to which the Relators may show that they are justly entitled.

Respectfully submitted,

8-31-16
Date

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